Ultrafen®

Tablet / SR Tablet / Suppository / Gel

Description

Ultrafen is a preparation of Diclofenac is a non-steroidal anti-inflammatory agent with marked analgesic, anti-inflammatory and antipyretic properties.

Indications

Rheumatoid arthritis, osteoarthritis, low back pain and other acute musculo-skeletal disorders such as frozen shoulder, tendinitis, teno-synovitis, bursitis, sprain, strain and dislocation, ankylosing spondylitis, acute gout, pain in orthopaedics, dental and other minor surgery.

Dosage and Administration

Adults

→ Enteric coated tablet : A total of 75-150 mg daily given in two or three divided doses.

→ Sustained release tablets : One tablet daily, taken whole with liquid, preferably during meal.

→ Suppositories : 75-150 mg daily in divided doses.

→ Gel : Depending on the painful site to be treated, 2-4 g gel may be applied 3-4 times daily.

Children

→ Enteric coated tablet : 1-3 mg / kg per day in divided doses.

→ Sustained release tablets : Not recommended.

→ Suppositories : 1-3 mg / kg body weight in divided doses.

Contraindication

Ultrafen should not be given in patients with previous hypersensitivity to Diclofenac, asthmatic patients and in whom attacks of asthma, urticaria or acute rhinitis are precipitated by Aspirin or other NSAIDs.

Precautions

Ultrafen should not be prescribed to pregnant women unless there is compelling reason for doing so. Patients with a history of peptic ulcer, haematemesis, melaena, bleeding diathesis or with severe hepatic or renal insufficiency, should be kept under close surveillance. If abnormal liver function tests persist or worsen, clinical signs and symptoms consistent with liver disease or if other manifestations occur (eosinophilia, rash), Ultrafen should be discontinued. Use of Ultrafen in patients with hepatic porphyria may trigger an attack.

Side Effects

Epigastric pain, nausea and diarrhoea, headache and slight dizziness may be complained by some patients. These are often transient, disappearing with continuation of medication. Occasionally skin rash, peripheral oedema and abnormalities of serum transaminase have been reported. Very rarely reported side effects include activation of peptic ulcer, haematemesis or melaena, blood dyscrasia (in course of extensive usage). There have been isolated reports of anaphylactoid reactions.

Commercial Packs

Ultrafen® 25 Tablet : Box containing 10 blister strips of 10 enteric coated tablets, each tablet contains Diclofenac Sodium BP 25 mg.

Ultrafen® 50 Tablet : Box containing 10 blister strips of 10 enteric coated tablets, each tablet contains Diclofenac Sodium BP 50 mg.

Ultrafen® 100 SR Tablet : Box containing 10 blister strips of 10 sustained release tablets, each tablet contains Diclofenac Sodium BP 100 mg.

Ultrafen® 12.5 Suppository : Box containing 10 suppositories (2 x 5's), each suppository contains Diclofenac Sodium BP 12.5 mg.

Ultrafen® 50 Suppository : Box containing 10 suppositories (2 x 5's), each suppository contains Diclofenac Sodium BP 50 mg.

Ultrafen® 10 Gel : Tube containing 10 g Gel, each gram contains Diclofenac Diethylamine BP equivalent to Diclofenac Sodium 10 mg.

Ultrafen® 25 Gel : Tube containing 25 g Gel, each gram contains Diclofenac Diethylamine BP equivalent to Diclofenac Sodium 10 mg.

Ultrafen® IM Injection

Diclofenac Sodium

Description

Diclofenac is a non-steroidal anti-inflammatory agent with marked analgesic, anti-inflammatory and antipyretic properties. It also has some uricosuric effect. The actions of diclofenac appear to be associated principally with the inhibition of prostaglandin synthesis - by inhibiting cyclooxygenase - the enzyme that catalyzes the formation of prostaglandin precursors (endoperoxides) from arachidonic acid. Following oral administration, diclofenac is rapidly absorbed from the gastro-intestinal tract. Peak plasma concentration following ingestion of an enteric coated tablet occurs at about 2 to 3 hours and that following injection occurs within half an hour.

Indications

Ultrafen injection is used to relief all grades of pain and inflammation in a wide range of conditions including:

a) Arthritic conditions: Rheumatoid Arthritis, Osteoarthritis, Ankylosing spondylitis, Acute gout.

b) Acute musculoskeletal disorders such as periarthritis (e.g., frozen shoulder), tendinitis, tenosynovitis, bursitis.

c) Other painful conditions resulting from trauma including fracture, low back pain, sprains, strains, dislocations, orthopaedic, dental and other minor surgeries.

Dosage and Administration

Adults: One ampoule once (or in severe cases, twice) daily by intramuscular injection.

Renal colic: One ampoule once daily intramuscularly. A further ampoule may be administered after 30 minutes, if necessary.

The recommended maximum daily dose of diclofenac is 150 mg , by any route.

Children: In juvenile chronic arthritis, 1-3 mg of diclofenac / kg body wt. daily in divided doses.

Elderly patients: In elderly or debilitated patients, the lowest effective dosage is recommended, commensurate with age and physical status.

Contraindications

Diclofenac is contra-indicated for those patients who are hypersensitive to diclofenac. In patients with active or suspected peptic ulcer or gastro-intestinal bleeding or for those patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other NSAIDs possessing prostaglandin synthetase inhibiting activity, diclofenac is also contra-indicated.

Adverse Effects

Side-effects to diclofenac are usually mild and transient. However, if serious side-effects occur, diclofenac should be discontinued.

Gastrointestinal: Occasional : epigastric pain, other gastro-intestinal disorders (e.g., nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia).

Rare: gastro-intestinal bleeding, peptic ulcer (with or without bleeding or perforation), bloody diarrhoea.

In isolated cases: lower gut disorders (e.g., non-specific haemorrhagic colitis and exacerbations of ulcerative colitis or Crohn's proctocolitis), pancreatitis, glossitis, constipation etc.

Precautions

Renal: Patients with severe hepatic, cardiac or renal insufficiency or the elderly should be kept under close surveillance, since the use of NSAIDs may result in deterioration of renal function. The lowest effective dose should be used and renal function should be monitored.

Hepatic: If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), diclofenac should be discontinued.

Patients receiving long term treatment with NSAIDs should be monitored as a precautionary measure (e.g., renal, hepatic function and blood counts).

High risk group

Pregnancy & Lactation:

Diclofenac should not be prescribed during pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used. This type of drug is not recommended during the last trimester of pregnancy. Very small quantities of diclofenac may be detected in breast milk, but no undesirable effects on the infant are to be expected.

Since no experience has been acquired with diclofenac gel in pregnancy or lactation, it is not recommended for use in these circumstances.

Drug Interactions

Lithium and digoxin: Diclofenac may increase plasma concentrations of lithium and digoxin.

Anticoagulants: There are isolated reports of an increased risk of haemorrhage with the combined use of diclofenac and anticoagulant therapy, although clinical investigations do not appear to indicate any influence on anticoagulant effect.

Antidiabetic agents: Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effects.

Cyclosporin: Cases of nephrotoxicity have been reported in patients receiving cyclosporin and diclofenac concomitantly.

Methotrexate: Cases of serious toxicity have been reported when methotrexate and NSAIDs are given within 24 hours with each other.

Quinolone antimicrobials: Convulsions may occur due to an interaction between quinolones and NSAIDs. Therefore, caution should be exercised when considering concomitant therapy of NSAID and quinolones.

Other NSAIDs and steroids ; Co-administration of diclofenac with other systemic NSAIDs and steroids may increase the frequency of unwanted effects. With aspirin, the plasma levels of each is lowered, although no clinical significance is known.

Diuretics: Various NSAIDs are liable to inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels. So, serum potassium should be monitored.

Pharmaceutical Precautions

Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack

Ultrafen IM Injection: Box containing 2 x 5 ampoules of 3 ml in blister pack. Each 3 ml ampoule contains Diclofenac Sodium BP 75 mg.

Manufactured by

beximco pharmaceuticals ltd.

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